# BREATHING DISORDER DETECTION AND THERAPY DELIVERY DEVICE AND METHOD

## Field of the Invention:

The invention relates to a device and method for detection, diagnosis and treatment of breathing insufficiencies or irregularities and to the management of pulmonary rhythm. Such irregularities may include, for example, hyperventilation, hypoventilation and apnea. The invention also relates to stimulating respiration in response to detecting hypoventilation or apnea.

## Background of the Invention:

Breathing insufficiencies and irregularities may occur in conjunction with or as a result of a variety health related disorders and may further cause or exacerbate health disorders. Such breathing insufficiencies and irregularities may include, for example, hyperventilation, hypoventilation, apnea, and other related breathing disorders. Hyperventilation, which results in hyperoxia, is a condition in which the respiratory rate is pathologically high or is above a desired rate. Hyperventilation may occur due to pulmonary edema or excess fluid built up in the lungs and may ultimately result in apnea episodes. Hypoventilation is a condition in which the respiratory rate is pathologically low or below a desired rate. Apnea (absence of breathing) is a breathing disorder most typically occurring during sleep that can result from a variety of conditions. Sleep apnea typically results in some sort of arousal or wakefulness following cessation of breathing.

Sleep disordered breathing disorders include two types of sleep apnea: obstructive sleep apnea (partial apnea or obstructive apnea) and central sleep apnea. Obstructive sleep apneas result from narrowing of the pharynx with out-of-phase breathing in an effort to create airflow, whereas central sleep apnea arises from reductions in central respiratory drive. During obstructive sleep apnea, respiratory effort increases. In central sleep apnea, respiratory movements are absent or attenuated but in phase.

Disordered breathing may contribute to a number of adverse cardiovascular outcomes such as hypertension, stroke, congestive heart failure, and myocardial infarction. Sleep-related breathing disorders, especially central sleep apnea, have been found to have a relatively high prevalence in patients with heart failure and may have a causative or influencing effect on heart failure. In about 50% of patients with stable congestive heart failure, there is an associated sleep disordered breathing, predominantly central sleep apnea with a minority having obstructive sleep apnea. Furthermore, sleep related breathing disorders are believed to be physiologically linked with heart failure. Central sleep apnea is a known risk factor for diminished life expectancy in heart failure. It is also believed that in view of this link, treatment aimed at relieving sleep related breathing disorders may improve cardiovascular outcomes in patients with heart failure.

Pulmonary edema, a condition in which there is excess fluid in the lungs and often found in heart failure patients, is believed in some circumstances to lead to hyperventilation and hyperoxia or apnea. Most heart

2

failure patients with central sleep apnea, when lying flat, tend to have central fluid accumulation and pulmonary congestion, which stimulates vagal irritant receptors in the lungs to cause reflex hyperventilation. Central Sleep

5   Apneas usually are initiated by reduction in $PCO_2$ resulting from the increase in ventilation. When $PCO_2$ falls below the threshold level required to stimulate breathing, the central drive to respiratory muscles and airflow cease or diminish significantly and apnea (or attenuated breathing)

10  ensues until the $PCO_2$ rises again above the threshold required to stimulate ventilation. Often spontaneous arousal occurs with apnea.

Currently a number of methods are used to treat sleep apnea. For example, supplemental oxygen such as, e.g.,

15  with a nasal ventilator, has been used to relieve symptoms of sleep apnea. Non-invasive airway pressure including continuous positive airway pressure (CPAP), bivalve and adaptive pressure support servo-ventilation have been used to treat central sleep apnea and obstructive sleep apnea

20  with varying results. Another method to treat central sleep apnea is using aggressive diuresis to lower cardiac filling and beta-blocker and angiotensin-converting enzymes. However, this treatment does not lead to an optimum therapy since excessive use of diuretics leads to

25  renal complications and patient discomfort.

A method and apparatus for treatment of obstructive sleep apnea has been proposed where an implantable pulse generator stimulates a nerve in the upper airway tract of a patient to elicit a contraction by an innervated muscle

30  through the provision of electrical stimuli. The stimulator is intended to treat the obstructed airway passage to permit breathing. The pulse generator is

3

attached to electrodes placed on the patient's diaphragm for sensing the respiratory effort of a patient whereupon the stimulation is adjusted. The method and apparatus do not provide a satisfactory treatment of central sleep apnea.

Phrenic nerve stimulation has been used to stimulate the diaphragm throughout an overnight period to treat sleep apnea. The device used was turned on at night to stimulate the nerve continuously and then turned off during the day. However, this device was not adapted for situations where patients would breath spontaneously.

Accordingly it would be desirable to provide a method and apparatus for treating breathing disorders such as apnea, and hypoventilation, and especially central sleep apnea. Furthermore it would be desirable to provide treatments for breathing related disorders related pulmonary edema and conditions in heart failure patients.

Summary of the Invention:

The present invention provides a method and apparatus for treating breathing disorders by sensing the respiratory parameters of the diaphragm and stimulating an associated body organ or tissue to control movement of the diaphragm and thus manage respiration. In a variation, the method and apparatus provide stimulation to the diaphragm to elicit diaphragm movement to cause respiration when respiration ceases or falls below a threshold level.

One embodiment is a device comprising: a sensor for sensing information corresponding to respiratory effort of the diaphragm and a processor for processing the sensed information and delivering electrical stimulating pulses to the associated body organ or tissue based on sensed

4

information. The processor may further determine
stimulation parameters based at least in part on sensed
information. Also, the processor may determine when to
cease stimulation by determining when the body resumes

5    normal respiratory function.

The respiratory effort may be sensed, for example, by
sensing the phrenic nerve activity and/or the EMG of the
diaphragm, or by detecting movement of the diaphragm or
chest. Respiration by the diaphragm may be stimulated by

10   electrically stimulating the phrenic nerve and/or by
stimulating the diaphragm muscle.

A number of different parameters may be programmed
into the processor to determine if certain breathing
disorders are present, and when and how to stimulate

15   respiration, and when to stop or modify stimulation.

Phrenic nerve or EMG activity sensed may include, for
example, amplitude, frequency, and waveform to determine
central respiratory efforts, the absence, a decrease in
amplitude, abnormalities in frequency and/or amplitude, or

20   waveform morphology of which may indicate the onset of
apnea, hyperventilation, or hypoventilation. The nerve
activity may be compared to predetermined activity levels
or patient historical activity. Similarly, diaphragm EMG
amplitude, frequency, waveform morphology and history may

25   be used to determine apnea, hyperventilation and
hypoventilation. For example, the nerve activity at the
onset of sleep or after a given time in a reclining
position, may be used as a baseline for comparison.

An awake sinus zone may be defined as a respiratory

30   rate or range of rates programmed into the device for a
specific patient when awake, where the respiratory rate is
considered normal and intrinsic. A preprogrammed EMG

amplitude or range may define a normal range in this state. A sleep sinus may be defined as a respiratory rate or range of rates programmed into the device for a specific patient when asleep where the respiratory rate is considered normal

5 and intrinsic. A preprogrammed EMG amplitude or range may define a normal range in this state. The device may be programmed to match the EMG rate and amplitude to a normal rate and amplitude by auto adjusting the pace output.

Hypoventilation may be detected where the respiratory

10 rate or frequency falls below a programmed rate. Hyperventilation may be detected when the respiratory rate or frequency is above a programmed rate. Complete apnea or central apnea is defined as a condition where there is no effective EMG signal or phrenic nerve signal, i.e. where

15 there is no effective or significant physiological response. Frequently, a hyperventilation episode is followed by loss of diaphragm EMG or phrenic nerve activity. The device may be programmed to first detect the hyperventilation and wait for a preprogrammed time to be

20 considered apnea. For example the time may be set to 10-20 seconds of lost EMG after a hyperventilation episode to detect complete apnea. Partial apnea or obstructive sleep apnea is defined to be present when the EMG or phrenic nerve activity is attenuated and may be detected when the

25 amplitude drops below a programmed amount. For example such amount may be based on the EMG or phrenic nerve amplitude dropping a percentage, e.g. 50% of the Sleep Sinus EMG amplitude. Also the phase of the respiratory cycles in partial apnea may be determined or compared to an

30 in phase cycle. An out of phase or arrhythmic cycle may also be used to detect partial apnea.

6

In addition, position sensors may be used to determine degree of patient reclining or standing, e.g., in increments of degrees. Information from the position sensor may be used as a tool to match respiratory activities and patterns to the position of the patient. Accelerometer information may be used to determine information regarding patient's physical activity, e.g., to match/compare to the respiratory patterns and activities and collect data on related patient activities, respiratory activities, and create or adjust a treatment plan based thereon, (e.g., modification of diuretics or ACE inhibitors). Accelerometer sensors may also be used to determine information regarding movement pattern of the diaphragm muscles, intercostal muscles, and rib movement and thus determine overall respiratory activity and patterns.

According to an embodiment, a stimulator includes an implantable controller coupled through leads to electrodes to be implanted on the diaphragm in the vicinity of the phrenic nerve branches. The electrodes may sense either nerve activity or EMG signals of the diaphragm. The stimulator may further include a pulse generator configured to deliver stimulating pulses, either to the same electrodes used for sensing or to additional stimulation electrodes. The stimulation electrodes may also be placed adjacent the phrenic nerve at some point along its length to provide stimulation pulse to the nerves, which in turn enervate the diaphragm muscle causing contractions and resulting respiration. Alternatively the electrodes may be placed on the phrenic nerve for both sensing and stimulation.

7

Stimulation of respiration may be initiated when "no" or "attenuated" respiratory activity has been present or detected for a time period (when apnea is detected). The time period may be pre-programmed for a specific patient by the physician, as otherwise preset, or as determined a program in the treatment device. The device may be programmable for other breathing disorders, allowing slow or fast inspiration and visa versa allowing slow or fast expiration. For example, based on programmed parameters of the activity sensor, for patients suffering from hypoventilation, the inspiration rate may be increased or decreased based on the level of activity.

Pacing starts at given intervals. In one embodiment the interval time is initially about 10 seconds. The interval is slowly increased from 11 seconds to about 15 seconds. If the patient does not breath on their own, the pacing begins again at 10-second intervals and this is repeated. If the patient begins breathing on their own, typically where the $Po_2$ and $PCO_2$ levels are normalized and the brain resumes sending nerve stimulation. The system then returns to the mode where it is sensing respiratory effort.

An additional feature of the invention may include a patient self-management module. The module can be an external device configured to telemetrically communicate with the implanted device. The module is configured to communicate information with the patient based on what is received from the implantable device. The information may also be communicated with a provider who can upload information regarding the status of the patient including urgent interventions. The device may include, paging, e-mail, fax or other communication capabilities that can send

8

information to a clinician.  The device can be worn or carried with the patient while the patient is away from home.  The device may be used to prompt the patient to comply with life-style and medication based on programmed

5 parameters by the provider.  The device may require the patient to interact with the device confirming compliance. The provider may receive information on patient compliance.

The information that may be downloaded for sleep apnea treatment may include, e.g., detection rate, detection

10 amplitude, pacing therapy amplitude, pacing pulse width, pacing frequency or other stimulation waveform morphology. This information may be used to calibrate device detection and therapy parameters.

The information that may be downloaded for pulmonary

15 edema management (e.g., of hyperventilation rate and frequency of occurrence) may include the detections rate, detection amplitude, ventilation waveform morphology including slopes and surface of inspiration waveform, slopes and surface area of exhalation waveform, recorded

20 respiratory waveform information in conjunction with activity and position sensors information.  A provider may use the information in developing an optimum treatment plan for the patient including drug titrations for diuretic management as well as if patient is in need of urgent

25 attention leading to hospitalization, which is a frequent occurrence with heart failure patients dealing with pulmonary edema.  The patient compliance information may also be used for understanding the drug regimen effectiveness if patient complies or educate the patient

30 when there is lack of compliance with the therapy plan.


Detailed Description of the Drawings:

9

Figure 1 illustrates a sleep breathing disorder treatment device in accordance with the invention placed on the diaphragm.

Figure 5 illustrates an electrode assembly in accordance with the invention implanted on the abdominal side of the diaphragm.

Figure 3 illustrates a sleep breathing disorder treatment device in accordance with the invention placed on the phrenic nerves.

Figure 4 illustrates a sleep breathing disorder treatment device in accordance with the invention placed on the diaphragm and phrenic nerves.

Figure 5 illustrates a sleep breathing disorder treatment device in accordance with the invention placed on the phrenic nerves.

Figure 6 illustrates a processor unit of a sleep breathing disorder treatment device in accordance with the invention.

Figure 7A is a schematic of a signal processor of the processor unit in accordance with the invention.

Figure 7B is an example of a waveform of an integrated signal processed by the signal processor of Figure7A.

Figure 8 is a schematic of an external device of a stimulator in accordance with the invention.

Figures 9A-9D are flow diagrams of the operation of a stimulator in accordance with the invention.

Figure 9B is a flow diagram of sleep apnea treatment with a stimulator in accordance with the invention.

Figure 9C is a flow diagram of hypoventilation treatment with a stimulator in accordance with the invention.

Figure 9D is a flow diagram of hyperventilation treatment with a stimulator in accordance with the invention.

Figures 10A-10B are an illustration of a variety of stimulation bursts with different parameters (Figure 10B) corresponding to different resulting EMG signals (Figure 10A).

Detailed Description of the Invention:

Figure 1 illustrates a stimulator 20 comprising electrode assemblies 21, 22, each comprising a plurality of electrodes 21a-d and 22a-d respectively. The electrode assemblies 21, 22 are implanted in the diaphragm muscle so that one or more of electrodes 21a-d and of electrodes 22a-d are approximately adjacent to one or more junctions of the phrenic nerves 15, 16, respectively, with the diaphragm 18 muscle. The electrode assemblies 21, 22 sense and pace at the diaphragm muscle. They are implanted laparoscopically through the abdomen and into the muscle of the diaphragm 18 with needles or other similar devices. The electrode assemblies 21, 22 may be anchored with sutures, staples, or other anchoring mechanisms typically used with implantable EMG electrodes. The leads 23, 24 coupling the electrode assemblies 21, 22 to the control unit 100 are then routed subcutaneously to the side of the abdomen where a subcutaneous pocket is created for the control unit 100. The electrode assemblies 21, 22 are each flexible members (such as neurostimulation leads) with electrodes 21a-d, assembled about 5-20 mm apart from one another and electrodes 22a-d assembled about 5-20 mm apart from one another. The electrode assemblies 21, 22 are coupled via leads 23, 24 to control unit 100. The control

unit 100 is configured to receive and process signals corresponding to sensed nerve activity, and/or EMG of the diaphragm 18, to determine the respiratory parameters of the diaphragm 18 as described in more detail herein with

5    reference to Figures 6, 7A-7B and 9A-9D.

The electrodes assemblies 21, 22 are coupled via leads 23, 24 to input/output terminals 101, 102 of a control unit 100. The leads 23, 24 comprise a plurality of electrical connectors and corresponding lead wires, each coupled

10    individually to one of the electrodes 21a-d, 22a-d. The control unit 100 is implanted subcutaneously within the patient, for example in the chest region on top of the pectoral muscle. The control unit 100 is configured to receive sensed nerve electrical activity from the electrode

15    assemblies 21, 22, corresponding to respiratory effort of a patient. The control unit 100 includes a processor 105 (Figure 6) that delivers stimulation to the nerves 15,16 or diaphragm 18 in response to a sensed degree or absence of diaphragm respiratory effort as determined and processed by

20    the processor 105 and control unit 100 as described in more detail herein with reference to Figures 6, 7A-7B, 8 and 9A-9D.

The stimulator 20 also comprises movement detectors 25, 26, in this example, strain gauges included with the

25    electrode assemblies 21, 22 respectively and electrically connected through leads 23, 24 to the control unit 100. The movement detectors 25, 26 detect movement of the diaphragm 18 and thus the respiratory effort exerted by the diaphragm 18. The movement detectors 25, 26 sense

30    mechanical movement and deliver a corresponding electrical signal to the control unit 100 where the information is processed by the processor 105. The movement may be used

12

to qualify the electrical phrenic nerve or EMG signal sensed by the device to confirm inspiration or exhalation is occurring, e.g., by matching mechanical and electrical activities of the diaphragm.

5    Electrodes may be selected from the plurality of electrodes 21a-d and 22a-d (or electrodes 41a-h, 42 a-h, 61a-d, 62a-d, 71a-d, 72a-d in the other examples described herein) once implanted, to form bipolar or multipolar electrode pairs or groups that optimize the stimulation

10    response. Such desired response may include tidal volume, breathing rate and the slopes of the inhalation and exhalation curves. For example, a timed series of pulses may be used to create a desired respiratory inhalation and/or exhalation period. Testing the response may be done

15    by selecting a bipolar electrode pair from two of the multiple electrodes in an assembly or any other combination of electrodes to form at least one closed loop system, by selecting sequence of firing of electrode groups and by selecting stimulation parameters. The electrodes may be

20    selected by an algorithm programmed into the processor that determines the best location and sequence for stimulation and/or sensing nerve and/or EMG signals, e.g., by testing the response of the electrodes by sensing respiratory effort in response to stimulation pulses. Alternatively,

25    the selection process may occur using an external programmer that telemetrically communicates with the processor and instructs the processor to cause stimulation pulses to be delivered and the responses to be measured. From the measured responses, the external programmer may

30    determine the optimal electrode configuration, by selecting the electrodes to have an optimal response to a bipolar or multipolar delivery of stimulation.

13

Figure 2 illustrates a diaphragm electrode assembly 40 in accordance with the invention for placement on the diaphragm 18 for sensing and/or stimulation of the diaphragm and/or phrenic nerve endings located in the diaphragm 18. The assembly 40 comprises a right loop 41 and a left loop 42, each loop comprising a plurality of electrodes 41a-h and 42a-h, each having individual connectors and leads that form leads 43, 44 coupled to the control unit 100. The loops 41, 42 are similar to electrode assembles 41, 42 in that the electrodes are selectable by the control unit 100 to form electrode pairs, multiple electrode pairs, or multipolar electrode groups. Figure 2 illustrates right phrenic nerve endings 15a and left phrenic nerve endings 16a as well as the right phrenic nerve anterior branch 15b, and left phrenic nerve anterior branch 16b, located on the diaphragm abdominal surface 18s. The loops 41, 42 are flexible and are placed on the abdominal surface 18s of the diaphragm 18 on the right diaphragm 18r and left diaphragm 18l, respectively adjacent the right phrenic nerve endings 15a and left phrenic nerve endings 16a respectively. The flexibility of the loops 41, 42 permits the ability to form the loops is the shape most ideally suite for a particular patient. The loops 41, 42 are attached to the diaphragm 18 with sutures, staples or other attachment devices 19. Other shapes may be used as well, e.g. a loop with a branch that extends to the region adjacent the anterior branches 15b, 16b of the phrenic nerve. The control unit 100 may be programmed to activate the electrodes in a sequence that is determined to elicit the desired response from the diaphragm 18 as described above with reference to electrodes 21a-d, 22a-d and Figure 1.

14

Referring to Figure 3, a breathing disorder treatment apparatus 60 according to the invention is illustrated. The apparatus 60 comprises right and left electrode assemblies 61, 62 each comprising a plurality of electrodes
5    61a-61d and 62a-62d respectively. The electrodes assemblies 61, 62 are illustrated attached to the right and left phrenic nerves 15, 16, respectively at a location in the neck 17. The electrode assembly may be a curved cuff electrode that can be placed around the nerve.
10   Procedures for accessing and attaching such electrode assemblies are generally know, for example, as described in *Phrenic Nerve Stimulation For Diaphragm Pacing With a Spinal Cord Stimulator*, Sur. Neurol 2003:59: 128-32.

Figure 4 illustrates the device 60 of to Figure 3 with
15   electrode assemblies 61, 62 alternatively positioned within the thorax 19 on the phrenic nerves 15, 16. The electrode assemblies 61, 62 are placed thoracoscopically on the phrenic nerve using a procedure similar to that described in *Thoracoscopic Placement of Phrenic Nerve Electrodes for*
20   *Diaphragmatic Pacing in Children*; Journal of Pediatric Surgery, Vol. 37, No 7 (July), 2002: pp 974-978. The electrode assemblies 61, 62 are located between the third and fourth rib within the thorax 19. The stimulator 60 is used in a similar manner in this Figure 4 as it is with
25   reference to Figure 3.

Figure 5 illustrates a stimulator 70 in accordance with the invention. The stimulator comprises stimulating electrode assemblies 71, 72 implanted in the diaphragm in a manner similar to that described above with reference to
30   electrode assemblies 71, 72 in Figure 1. The electrode assemblies 71, 72 include electrodes 71a-d, 72a-d, configured to deliver stimulating pulses to the diaphragm

and or phrenic nerve branches or junctions with the
diaphragm to elicit a breathing response by causing the
diaphragm to move. The stimulator 70 further comprises
electrode sensor assemblies 75, 76 placed on the phrenic
5    nerve at the throat in a surgical procedure similar to that
described above with reference to Figure 1 and electrode
assemblies 71, 72. The sensor assemblies 75, 76 comprise a
plurality of electrodes that are positioned and configured
to sense electrical activity of the phrenic nerve to
10   determine central respiratory effort. In response to
sensed respiratory effort, the control unit 100 supplies
EMG and/or nerve stimulation to the muscles of the
diaphragm 18 and/or the phrenic nerve endings 15, 16
located in the diaphragm 18.
15        Figure 6 illustrates an implantable control unit 100.
The control unit 100 includes electronic circuitry capable
of generating and/or delivering electrical stimulation
pulses to the electrodes of electrode assemblies 21, 22,
41, 42, 61, 62, 71, 72 through leads 23, 24, 43, 44, 63,
20   64, 73, 74 respectively to cause a diaphragm respiratory
response in the patient. For purposes of illustration, in
Figure 6, the control unit 100 is illustrated coupled to
through leads 23, 24 to electrode assemblies 21, 22
respectively. Other leads 41, 42, 61, 62, 71, 72 as
25   described herein may be connected to inputs 101, 102.
     The control unit 100 comprises a processor 105 for
controlling the operations of the control unit 100. The
processor 105 and other electrical components of the
control unit are coordinated by an internal clock 110 and a
30   power source 111 such as, for example a battery source or
an inductive coupling component configured to receive power
from an inductively coupled external power source. The

16

processor 105 is coupled to a telemetry circuit 106 that includes a telemetry coil 107, a receiver circuit 108 for receiving and processing a telemetry signal that is converted to a digital signal and communicated to the

5      processor 105, and a transmitter circuit 109 for processing and delivering a signal from the processor 105 to the telemetry coil 107. The telemetry coil 107 is an RF coil or alternatively may be a magnetic coil. The telemetry circuit 106 is configured to receive externally transmitted

10     signals, e.g., containing programming or other instructions or information, programmed stimulation rates and pulse widths, electrode configurations, and other device performance details. The telemetry circuit is also configured to transmit telemetry signals that may contain,

15     e.g., modulated sensed and/or accumulated data such as sensed EMG activity, sensed nerve activity, sensed responses to stimulation, sensed position information, sensed movement information and episode counts or recordings.

20          The leads 23, 24 are coupled to inputs 101, 102 respectively, of the control unit 100, with each lead 23, 24 comprising a plurality of electrical conductors each corresponding to one of the electrodes or sensors (e.g., strain gauge) of the electrode assemblies 23, 24. Thus the

25     inputs 101, 102 comprise a plurality of inputs, each input corresponding to one of the electrodes or sensors. The signals sensed by the electrode assemblies 21, 22 are input into the control unit 100 through the inputs 101, 102. Each of the inputs are coupled to a separate input of a

30     signal processing circuit 116 (schematically illustrated in Figure 6 as one input) where the signals are then amplified, filtered, and further processed, and where

17

processed data is converted into a digital signal and input into the processor 105.  Each signal from each input is separately processed in the signal processing circuit 116.

The EMG/Phrenic nerve sensing has a dual channel sensor.  One corresponding to each lung/diaphragm side.  However, sensing can be accomplished using a single channel as the brain sends signals to the right and left diaphragm simultaneously.  Alternatively, the EMG or phrenic nerve collective may be sensed using a single channel.  Either a dual channel or single channel setting may be used and programmed.  The typical pulse width parameter will range from 0.5ms to 10 ms in increments of 50 µs.  The pulse amplitude is from about 0.1v to 5 volts in increments of 100 µV.  The refractory period is 1 to 10 seconds in increments of 1 second.  As described in more detail with reference to Figures 10A -10B herein the system may adjust the pace, pulse, frequency and amplitude to induce or control rate of the various portions of a respiratory cycle, e.g. slope of inspiration, fast exhalation, exhalation and tidal volume.  The system may also adjust the rate of the respiratory cycle.

The system EMG memory is programmable to pre-trigger and post trigger lengths of storage for sleep apnea episodes.  The pre-trigger events are the waveform signals and other sensed information observed transitioning to an event.  Post-trigger events are the waveforms and other sensed information observed after an event and/or after treatment of an event, to observe how the device operated.  Post-trigger recordings can confirm if the episode was successfully treated.  The pre-trigger and post-trigger time periods can be preprogrammed into the control unit 100.

18

The control unit 100 includes a position sensor 121 configured to sense a relative position of the patient, e.g. angular position, and provide a digital signal corresponding to the sensed position to the processor 105.

5      The control unit 100 also includes an accelerometer 122 configured to sense acceleration and movement of the patient and to provide a digital signal corresponding to the sensed movement to the processor 105. In addition, an accelerometer 122 is positioned within the control unit

10    100. The accelerometer 122 measures the activity levels of the patient and provides the signal to the processor 105 for use in further analysis. Using an accelerometer in the implanted device indicates the activity level of the patient in conjunction with breathing rate. The

15    accelerometer senses activity threshold as at rest, low medium or high depending on the programmed threshold value for a specific patient. Using the activity (accelerometer) sensor value and respiratory information, the health of the respiratory system may be evaluated and monitored. For

20    example, if a patient's respiratory rate increases with an increase in activity and decreases with a decrease in activity, within a normal range, the patient's system will be considered functioning normally. If the patient's respiratory rate is out of range or too high while the

25    activity sensor indicates at rest or low, then the patient may be suffering from pulmonary edema. Using this monitor, the effect of drug titrations, e.g., diuretic dosages, on a patient with pulmonary edema can be monitored. If the pulmonary edema patient's respiration is brought more

30    towards a normal range with a drug dose, then the drug treatment would be maintained. If the drug treatment did not effect breathing sufficiently then the drug dosage may

19

be increased. Accordingly, the drug dosage may vary with detected breathing irregularities.

A position sensor 121 is also located within the control unit 100 and has an output coupled to the processor
5   105. The position sensor senses the relative angle of the patients' position. The position sensor is used to detect a patient's relative position, e.g., horizontal, supine, or standing. An available position sensor is the Spectrol 601-1045 smart position sensor, self-contained device that
10   provides an analog output over a full range of 360 degrees without requiring external components.

The control unit 100 further includes a ROM memory 118 coupled to the processor 105 by way of a data bus. The ROM memory 118 provides program instructions to the control
15   unit 100 that direct the operation of the stimulator 40. The control unit 100 further comprises a first RAM memory 119 coupled via a data bus to the processor 105. The first RAM memory 119 may be programmed to provide certain stimulation parameters such as pulse or burst morphology;
20   frequency, pulse width, pulse amplitude, duration and a threshold or trigger to determine when to stimulate. A second RAM memory 120 (event memory) is provided to store sensed data sensed, e.g., by the electrodes 21a-d 22a-d, 41a-h 42a-h, 61a-d 62a-d, 71a-d, 72a-d  (EMG or nerve
25   activity), position sensor 121, diaphragm movement sensors or strain gauges 25, 26, or the accelerometer 122. These signals may be processed and used by the control unit 100 as programmed to determine if and when to stimulate or provide other feedback to the patient or clinician. Also
30   stored in RAM memory 120 may be the sensed waveforms for a given interval, and a count of the number of events or episodes over a given time as counted by the processor 105.

20

The system's memory will be programmable to store:  number
of sleep apnea episodes per night; pacing stimulation and
length of time; the systemic auto-correction (i.e., how
stimulus was adjusted, e.g., in amplitude frequency phase
5   or waveform, to reach a desired or intrinsic level
response); body resumption of breathing; the number of
apnea episodes with specific durations and averages and
trending information; hyperventilation episodes during
supine position; number of hyperventilation episodes during
10   sleep position; number of hyperventilation episodes during
vertical position; and patient information including the
medications and dosages and dates of changes.  These
signals and information may also be compiled in the memory
and downloaded telemetrically to an external device 140
15   when prompted by the external device 140.

An example of the circuits of the signal processing
circuit 116 corresponding to one of the EMG inputs for one
of the electrodes or pairs of electrodes of the assemblies
21, 22 is illustrated schematically in Figure 7A.  An EMG
20   signal is input into an amplifier 130 that amplifies the
signal.  The signal is then filtered to remove noise by
filter 131.  The amplified signal is rectified by a
rectifier 132, is converted by an A/D converter 133 and
then is integrated by integrator 134 to result in an
25   integrated signal from which respiratory information can be
ascertained.  The signal output of the integrator 134 is
then coupled to the processor 105 and provides a digital
signal corresponding to the integrated waveform to the
processor 105.  The signal output of the integrator 134 is
30   also coupled to a peak detector 135 that determines when
the inspiration period of a respiratory cycle has ended and
an expiration cycle has begun.  The signal output of the

21

integrator 134 is further coupled to a plurality of comparators 136, 137, 138, 139. The first comparator 136 determines when respiration (EMG signal or phrenic nerve signal) has been detected based on when an integrated

5 signal waveform amplitude has been detected that is greater than a percentage value of the peak of an intrinsic respiratory cycle or another predetermined amount (comp 1), for example between 1-25% of the intrinsic signal. In this example, the comparator is set at a value that is 10% of

10 the waveform of an intrinsic respiratory cycle. The second comparator 137 determines a value of the waveform amplitude (comp 2) when an integrated signal waveform amplitude has been detected that is at a predetermined percentage value of the peak of an intrinsic respiratory cycle or another

15 predetermined amount, for example between 75%-100% of the intrinsic signal. In this example, the comparator is set at a value that is 90% of the waveform of an intrinsic respiratory cycle. From this value and the comp 1 value, the slope of the inspiration period (between 10% and 90% in

20 this example) may be determined. This slope may provide valuable diagnostic information as it shows how quickly a patient inhales. After (or when) the peak detector detects the end of an inhalation period and the beginning of an exhalation period, the third comparator 138 determines an

25 upper value for the waveform amplitude during active exhalation period, for example between 100% and 75% of the peak value detected by the peak detector 135. Then a lower value (comp 4) of the waveform during the exhalation period is determined by the fourth comparator 139, which compares

30 the measured amplitude to a predetermined value, e.g. a percentage value of the peak amplitude. In this example the value is selected to be 10% of the peak value. In one

22

embodiment this value is selected to roughly coincide with the end of a fast exhalation period. From comp 3 and comp 4 values, the slope of the exhalation period (between 10% and 90% in this example) may be determined. This slope may

5    provide valuable diagnostic information as it shows how quickly a patient exhales.

Figure 7B illustrates two sequential integrated waveforms of exemplary integrated signals corresponding to two serial respiratory cycles, described in more detail

10   herein with reference to Figures 9A-9D. The waveform 170 has a baseline 170b, inspiration cycle 171, a measured inspiration cycle 172, a point of 10% of peak inspiration 173 (comp 1), a point of 90% of peak of inspiration 174 (comp 2), a peak 175 where inspiration ends and exhalation

15   begins, and exhalation cycle 176 a fast exhalation portion 177 of the exhalation cycle 176, a 90% of peak exhalation point 178 (comp 3), a 10% of peak exhalation point 179 (comp 4), an actual respiratory cycle 180 and a measured respiratory cycle 181. The second waveform 182 is

20   similarly shaped. The 10% inspiration 183 of the second waveform 182 marks the end of the measured respiratory cycle 181, while the 10% point 173 of the waveform 170 marks the beginning of the measured respiratory cycle 181.

The system may adjust the pace, pulse, frequency and

25   amplitude to induce slow and elongated inspiration period; and fast and short inspiration period. The system may match the intrinsic sleep or awake time tidal volume by adjusting the output energy while sensing the EMG or nerve amplitude. This may be done gradually by frequently

30   sensing and incrementally adjusting. The system may deliver elongated inspiration period while shortening the expiration period to control and manipulate the $PO_2$ and $PCO_2$

23

levels in the blood to overcome and treat apnea. The
system may deliver time and amplitude modulation output for
control of inspiration and exhalation periods. To increase
the inspiration period, the system may deliver fewer bursts
5    at lower amplitudes and higher frequencies. To create a
fast, short inspiration cycle, the system may deliver more
of bursts at higher amplitudes. The system may deliver
sequential low energy pacing output either from one or
multiple electrodes to control and manage the pulmonary
10   stretch receptor threshold levels to avoid or prevent the
collapse of the upper airways. Figure 10 illustrates a
variety of exemplary stimulation bursts and resulting
effective EMG that may be used to control the various
phases of the respiratory cycle, including, e.g., slope of
15   inspiration, fast exhalation, exhalation, tidal volume,
peak value, and rate of respiration.

Referring to Figures 10A-10B, a first intrinsic EMG
waveform 550 is illustrated in Figure 10A. A subsequent
EMG waveform 551 (Figure 10A) is illustrated in response to
20   a burst of pulses 561 (Figure 10B) of symmetric amplitude,
frequency and pulse width. A subsequent EMG waveform 552
is illustrated (Figure 10A) in response to burst of pulses
562 (Figure 10B). The resulting EMG waveform 552 (Figure
10A) has a flatter inspiration slope and expiration slope
25   and relatively lower peak amplitude. This particular
effect may be desirable to control breathing and create a
slower more gradual inspiration. The burst 562 (Figure
10B) comprises a series of pulses increasing in amplitude
and of a higher frequency than burst 561 (greater number of
30   pulses). The subsequent EMG waveform 553 (Figure 10A) has
a relatively sharp inspiration slope. The corresponding
burst 563 of pulses has fewer pulses (3) and higher

24

amplitude pulses. The effect of this burst 563 is to increase inspiration rate. The subsequent EMG waveform 554 (Figure 10A) has a relatively slow inspiration cycle as a result of a burst 564 (Figure 10B) with both increasing

5    amplitudes and longer pulse widths (and a greater pulse duration). These are a few examples of a multitude of possible variations of burst pulses that can be modified to control the inspiration, expiration, tidal volume (area under waveform curve) and other parameters of the

10   respiratory cycle by modifying frequency, amplitude, pulse width of the pulses within the burst and the duration of the burst to get a desired effect. These bursts can be modified and programmed into a stimulator and may vary from patient to patient.

15         In Figure 8 a circuit for an external device 140 is illustrated. The external device 140 comprises a processor 145 for controlling the operations of the external device. The processor 145 and other electrical components of the external device 140 are coordinated by an internal clock

20   150 and a power source 151. The processor 145 is coupled to a telemetry circuit 146 that includes a telemetry coil 147, a receiver circuit 148 for receiving and processing a telemetry signal that is converted to a digital signal and communicated to the processor 145, and a transmitter

25   circuit 149 for processing and delivering a signal from the processor 145 to the telemetry coil 146. The telemetry coil 147 is an RF coil or alternatively may be a magnetic coil depending on what type of coil the telemetry coil 107 of the implanted control unit 100 is. The telemetry

30   circuit 146 is configured to transmit signals to the implanted control unit 100 containing, e.g., programming or other instructions or information, programmed stimulation

25

rates and pulse widths, electrode configurations, and other device performance details. The telemetry circuit 146 is also configured to receive telemetry signals from the control unit 100 that may contain, e.g., sensed and/or

5 accumulated data such as sensed EMG activity, sensed nerve activity, sensed responses to stimulation, sensed position information, or sensed movement information. Other information such as frequency and time of apnea, number of apnea events detected in a time interval or during a sleep

10 cycle, parameter relating to pulmonary edema such as frequency of hyperventilation including time and patient position. This information may be stored in RAM event memory 158 or may be uploaded and through an external port 153 to a computer, or processor, either directly or through

15 a phone line or other communication device that may be coupled to the processor 145 through the external port 153. The external device 140 also includes ROM memory 157 for storing and providing operating instructions to the external device 140 and processor 145. The external device

20 also includes RAM event memory 158 for storing uploaded event information such as sensed information and data from the control unit, and RAM program memory 159 for system operations and future upgrades. The external device also includes a buffer 154 coupled to or that can be coupled

25 through a port to a user-operated device 155 such as a keypad input or other operation devices. Finally, the external device 140 includes a display device 156 (or a port where such device can be connected), e.g., for display visual, audible or tactile information, alarms or pages.

30 The external device 140 may take or operate in, one of several forms, e.g. for patient use, compliance or monitoring; and for health care provider use, monitoring,

26

diagnostic or treatment modification purposes. The information may be downloaded and analyzed by a patient home unit device such as a wearable unit like a pager, wristwatch or palm sized computer. The downloaded

5    information may present lifestyle modification, or compliance feedback. It may also alert the patient when the health care provider should be contacted, for example if there is malfunctioning of the device or worsening of the patient's condition. The system may prompt the

10   patients with voice, music or other audible alarms regarding compliance with medication, diet and exercise. Medication compliance is a major issue with heart failure patients due to the difficulties created for the patients by some medications. The patient hand held also provides

15   daily update regarding the status of the device and as well as whether patients need to see the physician and/or consuming more or less of a medication according to the programmed parameters by the physician inside the implantable device. The device may also manage a patient's

20   diuretic level in relationship to breathing frequency and character. The device may monitor the response of the treatment from measured parameters provided by the control unit 100 in response to diuretic usage that e.g., may be input by the patient. This system may also warn the

25   patient to check into a hospital based on physician command (programming). The system could also direct the patient to rest in different positions to alleviate the present problem until help arrives.

Another device that interfaces with the patient's home

30   unit may also be used to provide information to the clinicians. Such device may communicate, for example via an internet, phone or other communication device. It may

27

download information from the patient and/or upload information form the physician. It may provide physicians with information identifying when intervention may be necessary or to further diagnose a patient's condition.

5    The external device may be equipped with a palm pilot type device that connects to the phone line for downloading the patient specific information regarding patient's pulmonary status as well as of conditions including apnea, hypoventilation and hyperventilation, and whether the

10   parameters are programmed correctly. This device may allow for remote follow-up, continuous monitoring of the patient's hemodynamic status, effectiveness of the drug regime and in particular the management of diuretics where the apnea is influenced by pulmonary edema. The

15   information may be viewed by the clinician using a web browser anywhere in the world of the handheld can send a fax or notice to the physician's office once the parameters of interest are outside the programmed range. The physician may then request an office visit. The system

20   also can send a summarized report on weekly, biweekly, or monthly as routine update based on the decision of the physician programmed in the handheld device. Medication adjustment/ drug titration may be accomplished remotely. Hand-held communication protocol/technology may be magnetic

25   or RF.

     Figures 9A-9D illustrate the operation of a stimulator in accordance with the invention. The EMG monitoring is turned on or started 200. (Alternatively, or additionally, the phrenic nerve activity may be monitored in the

30   sequences described in Figures 9A-9D). As illustrated in Figure 9A-9B, the system is turned on and begins sensing respiratory effort. It determines the intrinsic rates of

28

breathing cycles including respiratory period, inhalation period and exhalation period, and stores the values in event memory (step 200). This may be done, e.g., by sensing when a patient is in a reclining position for a

5    predetermined period of time while their breathing normalizes to that near the breathing rate when sleeping. A threshold level is then calculated from the intrinsic rate at some level below the peak of the intrinsic respiratory effort level.

10    The presence of an EMG is detected 200 by detecting when the amplitude of the integrated waveform 170 reaches a predetermined level, e.g., at a percentage of the total amplitude, of the intrinsic waveform of the breathing rate when sleeping.

15    If there is no EMG detected 201 then the stimulator determines whether sleep apnea is present or not 300 by determining a lack of EMG or phrenic nerve activity in a given period of time, e.g., 5-10 seconds, or by an attenuated EMG, e.g., not reaching comp 1 or, e.g., not

20    reaching comp 2 in the case of partial apnea. If sleep apnea is present, then the stimulator goes to the apnea treatment module 301 or to a program where the apnea is treated (See Figure 9B). If sleep apnea is not detected, then the stimulator determines if hypoventilation is

25    present 400 by determining that the EMG is present at an intrinsic amplitude or percentage thereof, but the rate is lower than the intrinsic rate. If hypoventilation is present then the stimulator goes to the hypoventilation treatment module 401 or to a program where hypoventilation

30    is treated. (See Figure 9C.) If an EMG, apnea, and hypoventilation are not detected, then presumably the patient is not breathing or there is a malfunctioning of

29

the stimulator. If this is the case, the system may be programmed to do an emergency check of the components and then communicate to the patient or health care provider that the stimulator is malfunctioning and/or the patient is not breathing 250. This communication may be accomplished a number of ways via a variety of ongoing or periodic communication processes. The system may continue to listen for an EMG 201 after the system does and emergency check (step 250). After a given time or number of iterations of reaching step 250, the stimulator may sound an alarm.

If an EMG is detected at step 201, then the stimulator starts a respiratory timer 202 and the time and amplitude values are stored. The respiratory timer will determine the amount of time in one given breathing cycle between the detected beginning of inspiration, exhalation and the detected beginning of the inspiration of the next cycle. The inspiration timer will also be started 203. The inspiration timer will time the duration of inspiration when detected, as described with respect to step 201, until the peak of the inspiration or the beginning of expiration.

The slope of the inspiration cycle is determined 204 by determining the amplitude and time of that amplitude at a further point in time in the inspiration cycle (comp 2) from this information and the time and amplitude at the detection of the EMG (201).

A peak detector monitors the integrated waveform and determines when it has peaked 205, marking the end of inspiration and the beginning of expiration. When the peak is detected the time or duration of the inspiration cycle is stored along with the amplitude 206. The inspiration timer is then turned off 207 and the exhalation timer is started 208. In step 209 the values comp3 and comp 4 are

30

determined as a predetermined percentage to the peak value. In step 210, a comparator will then compare the amplitude of the signal during exhalation to a predetermined value or percentage of the total amplitude as measured at the peak

5   until that value is reached. This predetermined value is referred to herein as comp 3. The time is stored. In step 211, a comparator will then compare the amplitude of the signal during exhalation to a predetermined lower end value or percentage of the total amplitude as measured at the

10  peak until that value is reached. This predetermined value is referred to herein as comp 4. The stimulator then determines the slope of the exhalation cycle based on time and amplitude values of comp 3 and comp 4. The value for comp 4 may be selected to approximately mark the end of the

15  fast exhalation period of the exhalation cycle, which is the initial period where the exhalation is sharper. At this point, the exhalation timer is stopped and the amplitude value and time is stored 212. In step 213, the stimulator may then determine the inhalation period, the

20  exhalation period and the slope or curve characteristics of the breathing cycle during this time the slope of the waveform during either exhalation and/or inspiration may be recorded and analyzed to identify breathing irregularities. The inhalation period and exhalation period may be

25  respectively based on the time values between the beginning of inhalation (comp 1) and the peak, and the peak (for inspiration) and the beginning of the peak and the end of the fast exhalation period. Also, the inspiration and expiration periods may also respectively include a

30  calculation or approximation of the time between the actual beginning of inspiration to the detected beginning of inspiration and a calculation of the time between the end

31

of the fast exhalation (comp 4) and the end of the
exhalation period.  The slopes of each of the inspiration
periods and expiration periods may be calculated as well as
the determination of other waveform characteristics that
5    may provide useful diagnostic information.  After the end
of the fast exhalation period has been determined the
stimulator then determines the total respirator period.
After a first inhalation and exhalation cycle of a first
breath, the stimulator awaits to detect a second cycle.
10   The stimulator waits to detect the presence of a comp 1
value of an EMG 215.  If the EMG is present then the time
is stored, the respiratory timer is stopped, and the
respiratory period is stored 216.  The respiratory period
may be a measured time from the detection of an EMG of a
15   first waveform to the detection of an EMG of a second
waveform.  Alternatively, the respiratory period may be
determined by adding the initial undetected period of the
first waveform and subtracting the initial undetected
period of the second waveform.  The stimulator then
20   determines if there is hyperventilation 217 by determining
if the rate is a certain value or amount above the
intrinsic rate for the particular awake, sleep or other
state of the patient.  If hyperventilation is detected,
then the stimulator goes to the hyperventilation module 501
25   where hyperventilation is treated.  If no hyperventilation
is detected, the stimulator returns to its original
monitoring step 201 where it awaits the next EMG detection
and repeats the cycle.

Figure 9B illustrates the sleep apnea module 301.
30   When sleep apnea is detected 300, a determination is made
as to whether apnea is complete apnea 302.  Complete apnea
would be determined by a complete lack in effective or

detected EMG (or alternatively, phrenic nerve activity).
If the apnea is not sleep apnea then a determination is
made as to whether the apnea is partial apnea 320 where the
EMG signal is attenuated a predetermined amount.  If the
apnea is obstructive apnea, an out of phase EMG may be
detected as well.

If complete sleep apnea is detected 302, then the
pacing output parameters stored in RAM 120 are loaded 303,
e.g., into a register.  The pacing output is then delivered
304.  After delivering the pacing output to the phrenic
nerve and/or diaphragm muscle, the EMG is observed 305, if
the EMG is not approximately at the intrinsic sleep level,
then the parameters are adjusted to bring the EMG more
within the appropriate range 306 and elicit a response
closer to intrinsic breathing.  For example, if the
frequency or amplitude is too low, then the frequency or
amplitude of the pacing is adjusted upwards.  If the
frequency or amplitude is too high, then the frequency or
amplitude of the pacing is adjusted downward.  If the EMG
is approximately at the intrinsic sleep level 305, then the
monitoring period is increased by one second 307 (e.g., the
monitoring period may start at about 10 seconds with a
maximum at about 15 seconds).  The EMG is then monitored
again to see if apnea is present 308.  If it is then the
pacing output is continued 304.  If it is then, if the
monitoring period is not at a defined maximum 309 then the
monitoring period is increased one second and the EMG is
observed again 308 and as long as the EMG is present 308,
the stimulator will keep increasing the monitoring period
by one second 307 until the maximum monitoring period is
reached 309.  When the monitoring period does reach a
maximum level, the apnea is confirmed as being treated 310

33

by observing the EMG for a given period of time, e.g. for 3 consecutive EMG's. The parameters of stimulation and information regarding the episode are stored 311 in event RAM 119, and the system returns to EMG monitoring (step 200 of Figure 9A).

If complete sleep apnea is not detected 302 then the stimulator determines if partial apnea is present 320. If partial apnea is not present, the system returns to the emergency check 250 to see if the system is malfunctioning. If partial apnea is present, then the existing EMG parameters are determined 321 and the pacing parameters are adjusted based on the existing EMG 322 and are loaded 323 and are delivered 324. The existing EMG parameters may be determined a number of ways. The system may attempt to match the desired EMG with the pacing output by adding on to the existing EMG. One method may involve calculating the tidal volume based on the peak value of the existing EMG voltage output, pulse width, thus area under the respiration curve; calculating the pacing energy (amplitude and frequency) required to achieve the tidal volume (of an intrinsic sleep EMG); and increasing the EMG or pacing an increased calculated amount to achieve the desired tidal volume.

If after delivering the pacing output 324, the EMG is not at the intrinsic sleep level 325, then the parameters are adjusted to elicit the intrinsic response 331 and the parameters are loaded 3232 and delivered 324 again. If the EMG is at the intrinsic sleep level 325 then the monitoring period is increased by one second 326, and EMG observed again to determine if the partial apnea has been treated 327. If the apnea has not been treated, then the stimulator returns to delivering the pacing output 324. If

34

apnea has been treated and the monitoring period is not at the maximum 328 then the monitoring time is increased by one second 326, and partial apnea is detected 327, etc. until the monitoring period has reached its maximum time

5    328throughout which apnea is determined to have been successfully treated. After the maximum period is reached apnea treatment is confirmed 329 by observing the EMG a predetermined period of time afterwards, e.g., for three consecutive EMG's. The parameters and information

10   regarding the episode are then stored 330. The system then returns to detecting the EMG (step 200 of Figure 9A)

Figure 9C illustrates the hypoventilation module 401. After hypoventilation is detected 400 by comparing the breathing rate to a programmed low threshold breathing rate

15   for a particular condition or state (e.g., waking, resting or sleeping), a pacing output designed to elicit the intrinsic rate is loaded and is delivered to the phrenic nerve and/or diaphragm 403. The EMG is then sensed 404 and the EMG is compared to the intrinsic EMG amplitude and

20   waveform 405. The output of the amplitude, rate and pulse width are adjusted to match intrinsic EMG morphology 406. The monitoring period is then increased by one second 407. If the natural breathing rate has been restored for the maximum monitoring period, the stimulator returns to the

25   step of detecting presence of EMG (step 200, Figure 9A). If it has not, then the EMG is sensed again 404, compared to the intrinsic rate 405, adjusted if necessary 406, and the timer incremented again 407 until the natural breathing has been restored. 408.

30   Figure 9D illustrates the hyperventilation module 501. If hyperventilation is present 500, then the level of hyperventilation is classified as Class I (low), Class II

35

(medium) or Class III (high) based on the rate an frequency
of hyperventilation.  These particular rates and
classifications may vary from patient to patient and may be
programmed in by the health care provider.  The time date,
respiratory rate, frequency of hyperventilation and
activity sensor are sensed and stored in event RAM 119.  If
class I is determined 504, the patient is informed via the
handheld or home monitoring device 505 and the patient is
notified to further comply with diuretic medications 506.
If class II is detected 507, then the patient is informed
and additional medication is recommended based on a
prescription programmed into the hand held device 508.  The
device then requests feedback by way of the hand held
device, regarding compliance 509.  The health care provider
is notified of the status by way of the remote system,
telephone connection or otherwise, and the sensed
information concerning the patient's status is uploaded
510.  If class III is detected 511, then the patient is
requested to visit the physician immediately and also to
consume addition medication according to the physician's
recommendation 512.  The health care provider is notified
via the remote system 512.  The system then returns to
detecting and EMG (step 200, Figure 9A).

While the invention has been described with reference
to particular embodiments, it will be understood to one
skilled in the art that variations and modifications may be
made in form and detail without departing from the spirit
and scope of the invention.